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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,441	05/10/2000	LASZLO BALAZS	1060-136P	1924

2292 7590 07/15/2003

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/15/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/485,441

Applicant(s)

BALAZS et al.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 26, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s):
see attached ADVISORY ACTION
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached ADVISORY ACTION

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1, 9, and 16-19

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

Brenda Coleman
BRENDA COLEMAN
PRIMARY EXAMINER
ART UNIT 1624

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ADVISORY ACTION

The shortened statutory period for response expires THREE MONTHS from the date of the final rejection or as of the mailing date of this advisory action, whichever is later. In no event however, will the statutory period for response expire later than SIX MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee.

Any extension fee required pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for response expires as set forth above.

The amendment filed June 26, 2003 under 37 CFR 1.116 in response to the final rejection **has been** considered and **entered**, however the amendment is not sufficient to place the application in condition for allowance.

Response to Amendment

Applicant's amendment June 26, 2003 has been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled paragraph 5 of the last office action, which is hereby **withdrawn**.
2. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph new matter rejections labeled 6a) and 6b) of the last office action, which are hereby **withdrawn**.

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However, with regards to the 35 USC § 112, first paragraph rejection of claims 1, 8, 9, 16 and 17 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants indicated that "this definition of R² and R³ is supported by the compound name 1-[2-(5-(4-aminophenyl)-8-methyl-7H-1,3-dioxolo-(4,5-h)(2,3)-benzodiazepine-7-yl)-2-oxoethyl]pyrrolidine-2-one". The definition of R² and R³ where R² and R³ is a 5-6 membered heterocyclic group having an oxo substituent are not included in the specific moieties described in the specification with respect to formula (I). The definition of R² and R³ in claims 1, 9, 16, 17 and 19, i.e. (a) is part of a single species with specific variables, not the description of the genus of formula I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

Claims 1, 9, 16, 17 and newly added claim 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

3. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled 7a), 7c), 7d), 7e), 7f), 7g), 7h), 7i), 7j), 7k), 7l), 7m), 7n), 7o), 7p), 7q), 7r), 7s) and 7t) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled 7b) and 7u) in the last office

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action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- b) The applicants' stated that the typographical error has been corrected. However, claims 9 and 16 have not been amended with respect to the rejection of the term "sutstituent in the definitions of R^2 and R^3 within the proviso.
- u) The applicants' failed to address this rejection, i.e. the use of / in the nomenclature of the species.

Claims 9, 16 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- 4. The applicant's amendments are sufficient to overcome the 35 USC § 101, utility rejection labeled paragraph 8 of the last office action, which is hereby **withdrawn**.

In view of the amendment dated June 26, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 19 recites the limitation "compound of formula I" in the process of preparing 1,3-dioxolo-[4,5-h][2,3]benzodiazepine. There is insufficient antecedent basis for this limitation in the claim. There is no formula I in claim 19.
- b) Claim 19 is vague and indefinite in that it is not known what is meant by the periods after a, b, c and d.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim begins with a capital letter and ends with a period. **Periods may not be used elsewhere in the claims** except for abbreviations. See *Fressola v. Manbeck*, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

- c) Claim 19 is vague and indefinite in that it is not known what is meant by the different definition for the variables R¹, n, X and Y. See lines 2-4 and 11-13 on page 9; lines 1, 4 and 9-11 on page 10; lines 4, 6-8, 12 and 15 on page 11; and line 3 on page 12.


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- d) Claim 19 is vague and indefinite in that it is not known what is meant by the different definition for the variable R^5 . See line 9 on page 9; line 16 on page 9 through line 1 on page 10; and line 4 on page 10.
- e) Claim 19 is vague and indefinite in that it is not known what is meant by R^2 and R^3 are as stated above, however, R^2 and R^3 are not stated above. See line 7 on page 10 and the last line on page 11.
- f) Claim 19 is vague and indefinite in that it is not known what is meant by the different definition for the variable W. See lines 3 and 11-12 on page 11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
July 11, 2003